

AMENDMENTS

In the Title:

Please amend the title to read --A Method of Treating Diabetes Mellitus in a Patient--.

In the Specification:

Please see the attached substitute specification.

In the Claims:

Please cancel claims 21-31 without prejudice and add the following new claims 32-52:

32. A method of treating diabetes mellitus in a patient in need thereof, said method comprising:

- (a) supplying a predetermined amount of insulin to a hand held device, said predetermined amount being in excess of that amount required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in said patient;
- (b) contacting said insulin with a compressed gas to form a cloud in said hand held device, said cloud comprising a repeatable amount of insulin, said repeatable amount being in excess of that amount required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in said patient; and
- (c) inhaling said cloud at an inspiratory flow rate and volume adapted to deliver a portion of said cloud to the lungs of said patient, wherein an amount of said insulin in said cloud effective, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in said patient is absorbed into the bloodstream of said patient.

33. A method of treating diabetes mellitus in a patient in need thereof, said method comprising:

- (a) supplying a predetermined amount of insulin to a hand held device, said predetermined amount being in excess of that amount required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in said patient;
- (b) contacting said insulin with a compressed gas to form a cloud in said hand held device, said cloud comprising a repeatable and controlled amount of insulin, said repeatable and controlled amount being in excess of that amount required, in the bloodstream of said patient, to produce or

maintain an acceptable serum glucose level in said patient; and

(c) inhaling said cloud at an inspiratory flow rate and volume adapted to deliver a portion of said cloud to the lungs of said patient, wherein an amount of insulin in said cloud effective, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in said patient is absorbed into the bloodstream of said patient.

34. A method of treating diabetes mellitus in a patient in need thereof, said method comprising:

(a) mechanically supplying a predetermined amount of insulin to a given area of a hand held device, said predetermined amount being in excess of that amount required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in said patient;

(b) aerosolizing said insulin with a compressed gas to form a cloud in said hand held device, said cloud comprising a repeatable and controlled amount of insulin, said repeatable and controlled amount being in excess of that amount required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in said patient; and

(c) inhaling said cloud at an inspiratory flow rate and volume adapted to deliver a portion of said cloud to the lungs of said patient, wherein an amount of insulin in said cloud effective, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in said patient is absorbed into the bloodstream of said patient.

35. A method of treating diabetes mellitus in a patient in need thereof, said method comprising:

(a) supplying a predetermined amount of insulin in the form of a dry powder to a hand held device, said predetermined amount being in excess of that amount required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in said patient;

(b) contacting said insulin with a compressed gas to form a cloud in said hand held device, said cloud comprising a repeatable and controlled amount of insulin, said repeatable and controlled amount being in excess of that amount required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in said patient; and

(c) inhaling said cloud at an inspiratory flow rate and volume adapted to deliver a portion of said cloud to the lungs of said patient, wherein an amount of insulin in said cloud effective, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in said patient is

absorbed into the bloodstream of said patient.

36. A method of treating diabetes mellitus in a patient in need thereof, said method comprising:

(a) mechanically supplying a predetermined amount of insulin in the form of a dry powder to a given area of a hand held device, said predetermined amount being in excess of that amount required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in said patient;

(b) aerosolizing said insulin with a compressed gas to form a cloud in said hand held device, said cloud comprising a repeatable and controlled amount of insulin, said repeatable and controlled amount being in excess of that amount required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in said patient; and

(c) inhaling said cloud at an inspiratory flow rate and volume adapted to deliver a portion of said cloud to the lungs of said patient, wherein an amount of insulin in said cloud effective, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in said patient is absorbed into the bloodstream of said patient.

37. A method of treating diabetes mellitus in a patient in need thereof, said method comprising:

(a) supplying a predetermined amount of insulin in the form of a dry powder to a hand held device, said predetermined amount being 2 to 10 times that amount required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in the blood of said patient;

(b) contacting said insulin with a compressed gas to form a dry cloud in said hand held device, said cloud comprising a repeatable and controlled amount of insulin, said repeatable and controlled amount being 2 to 10 times that amount required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in the blood of said patient; and

(c) inhaling said cloud at an inspiratory flow rate and volume adapted to deliver a portion of said cloud to the lungs of said patient, wherein an amount of insulin in said cloud effective, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in said patient is absorbed into the bloodstream of said patient.

38. A method of treating diabetes mellitus in a patient in need thereof, said method

comprising:

(a) mechanically supplying a predetermined amount of insulin in the form of a dry powder to a given area of a hand held device, said predetermined amount being 2 to 10 times that amount required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in said patient;

(b) aerosolizing said insulin with a compressed gas to form a dry cloud in said hand held device, said cloud comprising a repeatable and controlled amount of insulin, said repeatable and controlled amount being 2 to 10 times that amount required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in the blood of said patient; and

(c) inhaling said cloud at an inspiratory flow rate and volume adapted to deliver a portion of said cloud to the lungs of said patient, wherein an amount of insulin in said cloud effective, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in said patient is absorbed into the bloodstream of said patient.

§ 39. A method of treating diabetes mellitus in a patient in need thereof, said method comprising:

(a) supplying a predetermined amount of insulin in the form of a dry powder to a hand held device, said predetermined amount being 2 to 10 times that amount required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in said patient;

(b) contacting said insulin with a compressed gas to form a dry cloud in said hand held device, said cloud comprising a repeatable and controlled amount of insulin, said repeatable and controlled amount being 2 to 10 times that amount required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in the blood of said patient; and

(c) inhaling said cloud at an inspiratory flow rate and volume adapted to deliver a portion of said cloud to the lungs of said patient, wherein 1 to 30 units of insulin are absorbed into the bloodstream of said patient.

¶ 40. A method of treating diabetes mellitus in a patient in need thereof, said method comprising:

(a) mechanically supplying a predetermined amount of insulin in the form of a dry powder to a given area of a hand held device, said predetermined amount being 2 to 10 times that amount required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in said

patient;

(b) aerosolizing said insulin with a compressed gas to form a dry cloud in said hand held device, said cloud comprising a repeatable and controlled amount of insulin, said repeatable and controlled amount being 2 to 10 times that amount required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in the blood of said patient; and

(c) inhaling said cloud at an inspiratory flow rate and volume adapted to deliver a portion of said insulin cloud to the lungs of said patient, wherein 1 to 30 units of insulin are absorbed into the bloodstream of said patient.

41. A method of treating diabetes mellitus in a patient in need thereof, said method comprising:

(a) supplying a predetermined amount of insulin in the form of a dry powder to a hand held device, said predetermined amount being 2 to 300 units of insulin;

(b) contacting said insulin with a compressed gas to form a dry cloud in said hand held device, said cloud comprising a repeatable and controlled amount of insulin, said repeatable and controlled amount being 2 to 300 units of insulin; and

(c) inhaling said cloud at an inspiratory flow rate and volume adapted to deliver a portion of said cloud to the lungs of said patient; wherein 1 to 30 units of insulin are repeatably absorbed into the bloodstream of said patient.

42. A method of treating diabetes mellitus in a patient in need thereof, said method comprising:

(a) mechanically supplying a predetermined amount of insulin in the form of a dry powder to a given area of a hand held device, said predetermined amount being 2 to 300 units of insulin;

(b) aerosolizing said insulin with a compressed gas to form a dry cloud in said hand held device, said cloud comprising a repeatable and controlled amount of insulin, said repeatable and controlled amount being 2 to 300 units of insulin; and

(c) inhaling said cloud at an inspiratory flow rate and volume adapted to deliver a portion of said cloud to the lungs of said patient; wherein 1 to 30 units of insulin are repeatably absorbed into the bloodstream of said patient.

43. A method of treating diabetes mellitus in a patient in need thereof, said method

comprising:

- (a) determining the amount of insulin required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level;
- (b) aerosolizing, in a hand held device, a predetermined amount of insulin in excess of said required amount of insulin with a compressed gas to form a cloud in said hand held device, said cloud comprising a repeatable amount of insulin in excess of said required amount of insulin; and
- (c) inhaling said cloud at an inspiratory flow rate and volume adapted to deliver a portion of said insulin cloud to the lungs of said patient, wherein said required amount of insulin is absorbed into the bloodstream of said patient.

44. A method of treating diabetes mellitus in a patient in need thereof, said method comprising:

- (a) determining the amount of insulin required, in the bloodstream of said patient, to produce or maintain an acceptable blood glucose level;
- (b) aerosolizing, in a hand held device, a predetermined amount of insulin in excess of said required amount of insulin with a compressed gas to form a cloud in said hand held device, said cloud comprising a repeatable and controlled amount of insulin in excess of said required amount of insulin; and
- (c) inhaling said cloud at an inspiratory flow rate and volume adapted to deliver a portion of said cloud to the lungs of said patient, wherein said required amount of insulin is absorbed into the bloodstream of said patient.

45. A method of treating diabetes mellitus in a patient in need thereof, said method comprising:

- (a) determining the amount of insulin required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level;
- (b) aerosolizing, in a hand held device, a predetermined amount of insulin 2 to 10 times said required amount of insulin with a compressed gas to form a dry cloud in said hand held device, said cloud comprising a repeatable and controlled amount of insulin, said repeatable and controlled amount being 2 to 10 times said required amount of insulin; and
- (c) inhaling said cloud at an inspiratory flow rate and volume adapted to deliver a portion of said cloud to the lungs of said patient, wherein said required amount of insulin is absorbed into the

bloodstream of said patient.

15 46. A method of treating diabetes mellitus in a patient in need thereof, said method comprising:

(a) determining the amount of insulin required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level, said required amount being 1-30 units;

(b) aerosolizing, in a hand held device, a predetermined amount of a dry powder comprising insulin, said predetermined amount being 2 to 10 times said required amount of insulin, with a compressed gas to form a dry cloud in said hand held device, said cloud comprising a repeatable and controlled amount of insulin, said repeatable and controlled amount being 2 to 10 times said required amount of insulin; and

(c) inhaling said cloud at an inspiratory flow rate and volume adapted to deliver a portion of said cloud to the lungs of said patient, wherein from 1 to 30 units of insulin are absorbed into the bloodstream of said patient.

10 47. A method of treating diabetes mellitus in a patient in need thereof, said method comprising:

(a) determining the amount of insulin required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level, said required amount being from 1-30 units;

(b) aerosolizing, in said hand held device, a predetermined amount of insulin in the form of a dry powder, said predetermined amount being from 2 to 300 units of insulin, with a compressed gas to form a dry cloud in said hand held device, said cloud comprising a repeatable and controlled amount of insulin, said repeatable and controlled amount being from 2 to 300 units of insulin; and

(c) inhaling said cloud at an inspiratory flow rate and volume adapted to deliver a portion of said insulin cloud to the lungs of said patient; wherein from 1 to 30 units of insulin are repeatably absorbed into the bloodstream of said patient.

11 48. A method of treating diabetes mellitus in a patient in need thereof, said method comprising:

(a) aerosolizing, in a hand held device, a first predetermined amount of insulin, which is in excess of the amount of insulin required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level, with a compressed gas to form a first cloud in said hand held device,

said first cloud comprising a first repeatable and controlled amount of insulin which is in excess of the amount of insulin required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level;

(b) inhaling said first cloud at an inspiratory flow rate and volume adapted to deliver a portion of said first cloud to the lungs of said patient, wherein insulin is absorbed into the bloodstream of said patient; and

(c) repeating (a) and (b) with a second predetermined amount of insulin which is the same as or different from said first predetermined amount and is in excess of the amount of insulin required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level and a second repeatable and controlled amount of insulin which is the same as or different from said first repeatable and controlled amount and is in excess of the amount of insulin required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level.

49. A method of treating diabetes mellitus in a patient in need thereof, said method comprising:

(a) aerosolizing, in a hand held device, a first predetermined amount of insulin in the form of a dry powder with a compressed gas to form a first cloud in said hand held device, said first predetermined amount being an amount in excess of the amount of insulin required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level, said first cloud comprising a first repeatable and controlled amount of insulin which is in excess of the amount of insulin required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level;

(b) inhaling said first cloud at an inspiratory flow rate and volume adapted to deliver a portion of said first cloud to the lungs of said patient, wherein insulin is absorbed into the bloodstream of said patient; and

(c) repeating (a) and (b) with a second predetermined amount of insulin which is the same as or different from said first predetermined amount and is in excess of the amount of insulin required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level and a second repeatable and controlled amount of insulin which is the same as or different from said first repeatable and controlled amount and is in excess of the amount of insulin required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level.

50. A method of treating diabetes mellitus in a patient in need thereof, said method



comprising:

(a) aerosolizing, in a hand held device, a first predetermined amount of insulin in the form of a dry powder, said first predetermined amount being 2 to 10 times that amount required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in said patient, with a compressed gas to form a first dry cloud in said hand held device, said first cloud comprising a first repeatable and controlled amount of insulin which is 2 to 10 times that amount required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in said patient;

(b) inhaling said first cloud at an inspiratory flow rate and volume adapted to deliver a portion of said first cloud to the lungs of said patient, wherein insulin is absorbed into the bloodstream of said patient;

(c) repeating (a) and (b) with a second predetermined amount of insulin which is the same as or different from said first predetermined amount and is in excess of the amount of insulin required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level and a second repeatable and controlled amount of insulin which is the same as or different from said first repeatable and controlled amount and is in excess of the amount of insulin required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level.

20 51. A method of treating diabetes mellitus in a patient in need thereof, said method comprising:

(a) aerosolizing, in a hand held device, a first predetermined amount of insulin in the form of a dry powder, said first predetermined amount being 2 to 10 times that amount required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in said patient, with a compressed gas to form a first dry cloud in said hand held device, said first cloud comprising a first repeatable and controlled amount of insulin which is 2 to 10 times that amount required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in said patient;

(b) inhaling said first cloud at an inspiratory flow rate and volume adapted to deliver a portion of said first cloud to the lungs of said patient, wherein 1 to 30 units of insulin are absorbed into the bloodstream of said patient;

(c) repeating (a) and (b) with a second predetermined amount of insulin which is the same as or different from said first predetermined amount and is 2 to 10 times that amount of insulin required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level and a second repeatable and controlled amount of insulin which is the same as or different from said first repeatable

and controlled amount and is 2 to 10 times that amount of insulin required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level.

2^ 52. A method of treating diabetes mellitus in a patient in need thereof, said method comprising:

(a) aerosolizing, in a hand held device, a first predetermined amount of insulin in the form of a dry powder, said first predetermined amount being 2 to 300 units of insulin, with a compressed gas to form a first dry cloud in said hand held device, said first cloud comprising a first repeatable and controlled amount of insulin being 2 to 300 units of insulin;

(b) inhaling said first cloud at an inspiratory flow rate and volume adapted to deliver a portion of said first cloud to the lungs of said patient; wherein from 1 to 30 units of insulin are repeatably absorbed into the bloodstream of said patient;

(c) repeating (a) and (b) with a second predetermined amount which is the same as or different from said first predetermined amount and is 2 to 300 units of insulin and a second repeatable and controlled amount which is the same as or different from said first repeatable and controlled amount and is 2 to 300 units of insulin.